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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,105	02/06/2007	Beat A. Imhof	SER-108C1	3550
23557	7590	01/05/2010		
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614				
EXAMINER				
BASKAR, PADMAVATHI				
ART UNIT		PAPER NUMBER		
1645				
NOTIFICATION DATE		DELIVERY MODE		
01/05/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

### Office Action Summary

**Application No.**

10/579,105

**Applicant(s)**

IMHOF ET AL.

**Examiner**

Padma V. Baskar

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26, 27, 29 and 42-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26, 27, 29 and 42-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response and Amendment***

1. Applicant's amendment filed on 10/13/09 is acknowledged and entered.

***Status of claims***

2. Claims 1-25 and 30-41 are cancelled.  
Claims 26, 27, 29, 42 and 43 have been amended.  
New claims 46-55 have been added.  
Claims 26-27, 29, 42-55 are pending and are under examination.

***Double Patenting***

3. The obviousness-type double patenting rejection of claims 26-27, 29 and 46-55 is maintained for the same reasons as set forth in the previous office action.

Applicant states that applicant will file a terminal disclaimer (TD) over 10/738123 application once the patent number is known. The rejection is of record will be maintained until the office receives and approves the TD.

***Claim Rejections - 35 USC § 112 withdrawn***

4. In view of amendment to the claims, the rejection made under 35 U.S.C. 112, second paragraph is withdrawn.
5. In view of submission of a deposit declaration of record, the rejection of claims 26-27, 29, 42-45 under 35 U.S.C. § 112, first paragraph is withdrawn.

***Claim Rejections - 35 USC § 112 maintained***

6. The written description rejection of claims 26-27, 29, 42-45 and 51-55 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.
7. The enablement rejection of claims 26-27, 29, 42-55 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.

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Applicant argues that the amendments made to the claims have rendered this issue moot.

Applicants arguments are fully considered but have not been found persuasive because the specification fails to disclose  $V_{HS}$ ,  $V_{H\#1}$ , antibody having the same binding specificity of H33. The specification does not set forth structure or other physical characteristics and/or other chemical properties, by functional characteristics of said broadly claimed antibody. Further it is noted that mouse monoclonal antibody H33 and camel antibody  $V_{H\#1}$  /  $V_{HS}$  are structually different and thus binding specificity is not the same as H33. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

***Claim Rejections - 35 USC § 102 maintained***

8. The rejection of claims 26-27, 29, 42-45 and 54 under 35 U.S.C. § 102(b) as being anticipated by Aurrand-Lions et al in light of Bazzoni is maintained as set forth in the previous office action.

Applicant argues that Aurrand-Lions et al disclose a rat monoclonal antibody specific for JAM-C, in light of Bazzoni, including the 13H33 monoclonal antibody, however, the reference does not anticipate the claimed invention as the reference is not enabling because it fails to put the public in possession of the starting materials for the manufacture of the H33 antibody or the hybridoma producing the H33 antibody. In support of this, applicant cites several case laws of record.

The examiner has gone through the applicant's arguments and would like to bring applicant attention especially to claims 26, step (e) 42 and 54. The claims are broad and any antibody that binds to JAM-C would read on this as the specificity of H33 appears to be for JAM-C or epitope thereof. Therefore, the prior art rat monoclonal antibody that bind to JAM-C would read on the claimed invention and the art teaches how to make (materials and methods) and use said antibodies.

***New Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 26-27, 29, 42-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 26, step (d) iii recites "V<sub>H</sub>S". It is not clear what are the metes and bounds of "V<sub>H</sub>S".

**Claim Rejections - 35 USC § 103**

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 47, 55 and the dependent claim 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aurrand-Lions et al (in light of Bazzoni ) in view of Kucherlapati et al US-PAT-NO: 6075181.

Aurrand-Lions et al teach monoclonal antibodies specific for JAM-C, in light of Bazzoni (see e.g. Fig. 3). The prior art monoclonal antibody binds to JAM-C. However, the art does not teach human monoclonal antibody. Kucherlapati et al teach fully human monoclonal antibodies using Xenomice (disclosure of the invention, columns 4-7 and examples). The art suggests such antibodies are desirable for therapeutic and in vivo diagnostic use (see column 1, lines 49-52). One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to prepare human monoclonal antibody that binds to JAM-C because Aurrand-Lions et al teach monoclonal antibody binds to JAM-C and Kucherlapati et al teach how to make human monoclonal antibody and the use of said antibodies. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare human monoclonal antibody that binds to JAM-C in view of the teachings of Aurrand-Lions et al and Kucherlapati et al.

**Remarks**

13. No claims are allowed.

**Conclusion**

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

15. Papers related to this application may be submitted to Group 1600, AU 1165 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice

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published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor and Robert B. Mondesi on 571) 272-0956.

Respectfully,  
/Padma V Baskar/  
Examiner, Art Unit 1645

/Robert B Mondesi/  
Supervisory Patent Examiner, Art Unit 1645